PUBLISHED

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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_	No. 18-2409	
ACCIDENT, INJURY AND REHA	ABILITATION, PC, o	d/b/a Advantage Health &
Plaintiff - App	bellee,	
v.		
ALEX M. AZAR, II, Secretary of Human Services; SEEMA VERMA Medicaid Services,		•
Defendants - A	Appellants.	
Appeal from the United States Distribution Donald C. Coggins, Jr., District Jud		
Argued: September 18, 2019		Decided: November 21, 2019
Before WILKINSON, NIEMEYER	R, and AGEE, Circuit	Judges.
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ARGUED: Joshua Marc Salzman, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellants. Robert Bruce Wallace, Stephen Daniel Bittinger, NEXSEN PRUET, LLC, Charleston, South Carolina, for Appellee. **ON BRIEF:** Joseph H. Hunt, Assistant Attorney General, Mark B. Stern, Rachel F. Homer, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Sherri A. Lydon, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Columbia,

Preliminary injunction vacated by published opinion. Judge Niemeyer wrote the opinion,

in which Judge Wilkinson and Judge Agee joined.

South Carolina; Robert P. Charrow, General Counsel, Janice L. Hoffman, Associate General Counsel, Susan Maxson Lyons, Deputy Associate General Counsel for Litigation, Greg Bongiovanni, UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, Washington, D.C., for Appellants.

NIEMEYER, Circuit Judge:

According to the Department of Health and Human Services ("HHS"), healthcare provider Accident, Injury and Rehabilitation, P.C., d/b/a Advantage Health & Wellness ("Advantage Health"), was improperly paid over \$6 million for Medicare claims it submitted over a four-year period that did not qualify for reimbursement. HHS began recouping the overpayments from current Medicare reimbursements payable to Advantage Health, even as Advantage Health pursued appeals of HHS's initial overpayment determination through the administrative process. Because hearings before administrative law judges ("ALJs") — the third level of review in the administrative process provided by the Medicare Act — are currently severely backlogged, Advantage Health contends that HHS's continuing recoupment of overpayments before completion of the severely delayed administrative process is denying it procedural due process.

Advantage Health commenced this action in the district court, seeking injunctive relief prohibiting HHS from pursuing recoupment efforts until Advantage Health could challenge the recoupment amounts in a hearing before an ALJ. On Advantage Health's motion, the district court granted a preliminary injunction, enjoining HHS "from withholding Medicare payments to [Advantage Health] to effectuate recoupment of any alleged overpayments."

On HHS's appeal, we conclude that the injunction entered in this collateral proceeding, which prohibits HHS from recouping overpayments in accordance with applicable law, was inappropriately entered because the delay of which Advantage Health complains could have been and still can be avoided by bypassing an ALJ hearing and

obtaining judicial review on a relatively expeditious basis, as Congress has provided. *See Cumberland County Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 52–53, 55 (4th Cir. 2016) (noting that the "comprehensive" and "coherent" administrative process afforded by Congress includes mechanisms by which, in the event of a delay, healthcare providers may bypass certain levels of administrative review and obtain judicial review in "a relatively expeditious time frame"). Because we conclude that this administrative review process does not deny Advantage Health procedural due process, we vacate the district court's preliminary injunction.

I

Advantage Health is a South Carolina professional corporation that provides medical, chiropractic, and holistic care for patients in the Florence and greater Piedmont areas of South Carolina. Prior to 2015, it earned gross revenues of close to \$6.8 million per year, with approximately one-third of that sum derived from Medicare reimbursements.

Based on an analysis of Advantage Health's Medicare billings, the Medicare Program Integrity Coordinator for South Carolina, AdvanceMed, opened an investigation in September 2012 into Advantage Health's Medicare claims for reimbursement. That analysis indicated that Advantage Health had become "the top paid provider in South Carolina for physical therapy codes," but it did not appear to have sufficient growth in its patient population to justify its growth in reimbursement claims. Specifically, AdvanceMed found that "[f]rom 2010 to 2011, . . . the number of services [that Advantage Health] billed to Medicare increased 332%, and the amount paid to [it] increased 592% for

a patient population that only increased by an additional 35 beneficiaries." A follow-up analysis conducted months later showed that nurse practitioner "Judy Rabon . . . a member of [Advantage Health], was paid more than \$1.5 million for the years 2012 and 2013, averaging more than \$5,000 per beneficiary and billing more than 160 dates of service wherein more than 24 hours were billed in a day. A time study conducted on . . . Rabon indicated that the fewest hours billed by her on any given day was 15.8, with a maximum billed hours on any given day totaling 83.22."

In further pursuit of its investigation, AdvanceMed conducted an unannounced audit of an Advantage Health facility on July 1, 2013, during which it collected records relating to claims submitted during the period from June 2012 to April 2013 for services provided to 15 Medicare beneficiaries. After reviewing the records, AdvanceMed found that most of those claims should have been denied and that Advantage Health was accordingly overpaid \$2,507.91 in reimbursements.

Following that audit, on November 3, 2014, AdvanceMed issued a notice to Advantage Health suspending its Medicare reimbursements and requesting that it provide "a statistically valid random sample of medical records" relating to claims for services provided to 80 Medicare beneficiaries during the four-year period between September 2010 and September 2014. On receipt and review of the requested documents, AdvanceMed determined that 93.26% of the claims should have been denied and that Advantage Health had been overpaid a total of \$36,218.31. The reasons given for finding the claims ineligible for reimbursement included that the services provided by Advantage Health were not medically necessary, lacked documentation, were performed by unauthorized persons, or

were not covered by Medicare. From these data relating to the 80 Medicare beneficiaries, AdvanceMed extrapolated overpayments for the entire four-year period as to all claims that Advantage Health had submitted on behalf of Medicare beneficiaries, determining that Advantage Health had been overpaid a total of \$6,648,877.92 for Medicare services. It notified Advantage Health of this determination on June 8, 2015.

In accordance with the specified administrative review process, Advantage Health appealed AdvanceMed's overpayment determination to a Medicare Administrative Contractor. But in September 2015, the Medicare Administrative Contractor rejected Advantage Health's arguments for a redetermination of the overpayment amount. The Contractor also informed Advantage Health that it would seek to recoup the assessed overpayments through offsets to reimbursements for future Medicare claims submitted by Advantage Health.

Next, Advantage Health appealed further to the Medicare Qualified Independent Contractor ("QIC") for South Carolina, and that appeal automatically suspended HHS's recoupment efforts. After considering all records and other documents submitted by the parties, the QIC agreed with Advantage Health in part and overturned the denials of 13 individual claims, but it affirmed the vast majority of the denials. As a result of the QIC's ruling, AdvanceMed recalculated the total overpayment amount for which it was seeking recoupment on behalf of HHS.

From the QIC's ruling, Advantage Health appealed to the Office of Medicare Hearings and Appeals ("OMHA"), requesting a hearing before an ALJ. That hearing has yet to be scheduled, and, according to HHS, cannot be conducted before 2022 because of

the large backlog within OMHA. HHS attributes this backlog to the more than one *billion* Medicare claims per year that it must process.

As allowed by law, *see* 42 U.S.C. § 1395ddd, HHS had begun recouping funds overpaid to Advantage Health prior to 2015 by withholding payments for ongoing Medicare services. Even though it suspended collection during the pendency of Advantage Health's appeals to the Medicare Administrative Contractor and the QIC, it recovered over \$200,000 per year in 2014 and 2015. And after the QIC's decision was issued, when recoupment was no longer subject to suspension, HHS recouped over \$700,000 per year in 2016 and 2017. In total, it has recouped over \$1.8 million.

Advantage Health commenced this action against HHS and its agents on August 7, 2018, seeking injunctive relief to suspend HHS's recoupment efforts pending completion of the administrative process. The complaint alleges that "[t]he extraordinary amount (over \$6.6 million) that [HHS] is trying to recoup, coupled with the excessive backlog of claims before the OMHA, effectively strips Advantage Health of the administrative appeals due process to which it is entitled by statute." According to the complaint, the withholding of payments without providing a prompt ALJ hearing constitutes a denial of procedural due process, ultra vires action, and a violation of the Administrative Procedure Act. The complaint alleges further that, without interim relief from recoupment, Advantage Health will be "irreparably harmed before any meaningful opportunity for the administrative and judicial review to which it is entitled." According to its Chief Financial Officer, as a result of recoupment efforts, Advantage Health's gross revenues declined 50% in 2015, 48% in 2016, and 63% in 2017. In addition, it was forced to terminate 24 employees because of

declining revenues, and this reduction in staffing has, in turn, caused a two-thirds reduction in the number of patients it has treated. Advantage Health's Executive Director maintains that the corporation will be forced to cease operations if recoupment continues, despite an infusion of \$1.3 million in capital by its owner.

On Advantage Health's motion, the district court entered a preliminary injunction on September 27, 2018, enjoining HHS's recoupment efforts pending the ALJ hearing process. The court concluded that Advantage Health had made the requisite showing as to its due process claim. From the entry of that injunction, HHS filed this interlocutory appeal. *See* 28 U.S.C. § 1292(a).

II

Because this judicial proceeding implicates claims arising under the Medicare Act, HHS argued below that the district court lacked subject-matter jurisdiction. HHS cited 42 U.S.C. § 405(g) for the proposition that Advantage Health was required to exhaust the Act's administrative process before seeking judicial review. The district court rejected HHS's argument, and HHS does not challenge that ruling on appeal. Nonetheless, when subject-matter jurisdiction — which goes to the power of a court to act, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) — is questioned, we are obliged to allay that concern at the threshold, *see Gonzales v. Thaler*, 565 U.S. 134, 141 (2012) (noting that "when a requirement goes to subject-matter jurisdiction, courts are obligated to consider *sua sponte* issues that the parties have disclaimed or have not presented").

Section 405(g) provides that an individual may obtain judicial review of a claim arising under the Medicare Act only after receipt of a "final decision" by the Secretary of HHS. 42 U.S.C. § 405(g); *see also* 42 U.S.C. § 1395ff(b)(1)(A) (making § 405(g), a provision of the Social Security Act, applicable in the Medicare Act context). And, in this case, Advantage Health admittedly has not received a final decision from the Secretary. It has, at this point, requested a hearing before an ALJ, and that hearing has not yet been scheduled.

While the exhaustion requirement of § 405(g) is mandatory, it is well established that it is not jurisdictional. In *Mathews v. Eldridge*, 424 U.S. 319 (1976), the Supreme Court specifically held that the § 405(g) exhaustion requirement is not jurisdictional because its mandate can be waived, whereas a defect in the subject-matter jurisdiction of a court cannot be waived, either by the parties or the court. *See id.* at 330 (noting that an agency may waive the § 405g exhaustion requirement if it determines "that no further review is warranted either because the internal needs of the agency are fulfilled or because the relief that is sought is beyond [its] power to confer").

In addition, the *Mathews* Court noted that notwithstanding the requirements of § 405(g), courts need not wait for the agency's waiver or final decision of the Secretary "where a claimant's interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate." 424 U.S. at 330. Accordingly, "the exhaustion requirement of [§] 405(g) does not apply to a due process claim 'entirely collateral' to a substantive claim, if the plaintiff has raised 'at least a colorable claim' that erroneous deprivation prior to exhaustion of administrative remedies would harm him in a

way that could not be recompensed." *Ram v. Heckler*, 792 F.2d 444, 446 (4th Cir. 1986) (quoting *Mathews*, 424 U.S. at 330–31).

In this case, Advantage Health challenges, under the Due Process Clause, the method by which its claims for reimbursement are being reviewed. Because it does not challenge the substance of HHS's decision on the merits of those claims, its claim in this case is collateral insofar as its resolution does not require us to address the substantive issue of whether Advantage Health received reimbursements for ineligible claims. In addition, Advantage Health has raised at least a colorable claim that it faces irreparable harm during its wait for completion of the administrative process. Accordingly, we conclude that the district court had subject-matter jurisdiction to consider Advantage Health's claims and also that the court was not barred by § 405(g) from acting.

III

HHS contends on appeal that the district court abused its discretion in entering the preliminary injunction enjoining it from continuing its recoupment efforts because (1) Advantage Health has not demonstrated "a substantial likelihood of success on the merits of its procedural due process claim" and (2) it has not demonstrated "that it will suffer irreparable injury and that the balance of equities and public interest support an injunction."

Because a preliminary injunction affords temporary relief *before trial* of the type that can be granted permanently *after trial*, it is an "extraordinary remedy" and may be granted only "upon a clear showing that the plaintiff is entitled to such relief." *Winter v.*

Nat. Resources Def. Council, Inc., 555 U.S 7, 22 (2008). The party seeking a preliminary injunction must therefore demonstrate all of the following: (1) that it is likely to succeed on the merits of its claim; (2) that it is likely to suffer irreparable harm in the absence of a preliminary injunction; (3) that the balance of equities tips in its favor; and (4) that the injunction is in the public interest. See League of Women Voters of North Carolina v. North Carolina, 769 F.3d 224, 236 (4th Cir. 2014) (citing Winter, 555 U.S. at 20).

Against the backdrop of these requirements, HHS contends mainly that because Advantage Health has obtained two levels of administrative review of the overpayment determination and the two remaining levels of review can be bypassed in favor of prompt judicial review, its recoupment efforts during ongoing review "readily satisf[y] constitutional requirements." More specifically, it points out that the harm caused by the wait for an ALJ hearing, about which Advantage Health complains, can be mitigated by bypassing that level of review, as authorized by statute. See 42 U.S.C. § 1395ff(d)(3)(A). Noting that Advantage Health has elected not to pursue that course as a matter of preference, HHS argues that this strategic choice does not render the system constitutionally flawed and that Advantage Health cannot demonstrate that the administrative review process, taken as a whole, denies it due process. See Cumberland, 816 F.3d at 54 (demonstrating how a Medicare claimant can build an administrative record at the first two administrative levels and obtain judicial review of HHS's actions "within a relatively prompt time").

In response, Advantage Health contends that it has a property interest in Medicare reimbursements and that it must, as a matter of due process, be afforded a hearing before

the ALJ promptly if it will be deprived of such reimbursements through recoupment. It maintains that the first two levels of review are not sufficient to "satisfy Due Process," where, because of inordinate delay, it must forego an ALJ hearing in order to receive prompt post-deprivation review.

Advantage Health's argument, we conclude, focuses too narrowly on but a single element of a "comprehensive" and "coherent" administrative process for healthcare providers to obtain Medicare reimbursements and review of reimbursement decisions. Cumberland, 816 F.3d at 52 (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 569 (1995)). The process begins when a healthcare provider claims Medicare reimbursement from a Medicare Administrative Contractor for services provided to Medicare beneficiaries. The Medicare Administrative Contractor determines whether the claim meets the statutory criteria for reimbursement, and due to the high volume of claims processed by the Medicare program and to facilitate the prompt initial payment of Medicare claims, it generally makes an initial determination without reviewing supporting documentation. But the reimbursement the Contractor authorizes is nonetheless conditioned on HHS's right to audit the claim after payment and to recoup funds that have been paid in error. That audit is conducted by other government contractors, known as Program Integrity Contractors. See generally 42 U.S.C. § 1395ddd; 42 C.F.R. § 421.304. If the Program Integrity Contractor determines that a healthcare provider improperly received payment for a claim, HHS then seeks to recoup the funds that were paid in error.

After an initial determination of overpayment is made, the healthcare provider has four levels of administrative appeal by which it can challenge the determination. *First*, the

healthcare provider may seek a redetermination from the original Medicare Administrative Contractor. *See* 42 U.S.C. § 1395ff(a)(3). *Second*, the healthcare provider may seek review of the Medicare Administrative Contractor's determination by appealing to a QIC, which conducts a review of the "evidence and findings upon which the [determination] was based, and any additional evidence the parties submit or that [it] obtains on its own." 42 C.F.R. § 405.968(a)(1).

At each of these first two levels of review, the healthcare provider may submit any evidence it deems relevant and must explain its position in writing. *See* 42 C.F.R. § 405.946(a); *id.* § 405.966(a). The reviewer then issues a written decision that includes its reasoning. *See* 42 U.S.C. § 1395ff(a)(5); *id.* § 1395ff(c)(3)(E). Absent good cause, a healthcare provider may not, at a later level of review, rely on evidence that was not before or presented to the QIC at the second level of review. *See id.* § 1395ff(b)(3).

Third, a healthcare provider may seek further review before an ALJ, who conducts a hearing to review the QIC's decision. 42 U.S.C. § 1395ff(d)(1)(A). And *fourth*, the healthcare provider may appeal the ALJ's decision to the Departmental Appeals Board for a de novo review. *Id.* § 1395ff(d)(2). The Board's decision represents the Secretary's final decision and is subject to judicial review. *See* 42 C.F.R. § 405.1130.

The Medicare Act establishes deadlines for completion of each level of review and specifies the consequences if the deadlines are not met. We described this framework in *Cumberland*:

The Act directs that the first two steps of administrative review be completed by the Medicare Administrative Contractor and the QIC, respectively, within 60 days. 42 U.S.C. §§ 1395ff(a)(3)(C)(ii), 1395ff(c)(3)(C)(i). If the QIC

fails to meet this deadline, the healthcare provider may bypass the QIC determination and "escalate" the process by requesting a hearing before an ALJ, even though a decision by the QIC is ordinarily a prerequisite to such a hearing. Id. § 1395ff(c)(3)(C)(ii). With respect to the adjudication by an ALJ, the Medicare Act provides that an ALJ "shall conduct and conclude a hearing on a decision of a [QIC] . . . and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed." Id. § 1395ff(d)(1)(A); see also 42 C.F.R. § 405.1016(c) (providing a 180-day deadline if the appeal had been escalated past the QIC level). If the ALJ does not render a decision before the deadline, the healthcare provider may bypass the ALJ and again escalate the process by "request[ing] a review by the Departmental Appeals Board . . . , notwithstanding any requirements for a hearing for purposes of the party's right to such a review." 42 U.S.C. § 1395ff(d)(3)(A). Finally, if the Departmental Appeals Board does not conclude its review within 90 days, id. § 1395ff(d)(2)(A), or within 180 days if the appeal had been escalated past the ALJ level, 42 C.F.R. § 405.1100(d), the healthcare provider "may seek judicial review [in a United States district court], notwithstanding any requirements for a hearing for purposes of the party's right to such judicial review," 42 U.S.C. § 1395ff(d)(3)(B); see also 42 C.F.R. § 405.1132.

816 F.3d at 53–54 (alterations in original). In short, the administrative process not only creates deadlines for the completion of each step of the process but also anticipates that the deadlines may not be met, giving the healthcare provider the option of bypassing a delayed step by escalating the claim to the next level. In this manner, a healthcare provider can complete the administrative process and obtain judicial review "within a relatively prompt time," despite delays in interim steps. *Id.* at 54.

Advantage Health does not contend that HHS failed to follow the specified administrative process or that the process itself is unconstitutional. Indeed, Advantage Health continues to pursue that process in challenging HHS's overpayment determination. Rather, Advantage Health maintains that while it has received the first two levels of review, it is effectively being denied the third level — a hearing before the ALJ — because of the

long delay in holding that hearing and that this delay denies it procedural due process when HHS's recoupment efforts continue in the interim. It contends that a timely ALJ hearing is especially important to due process because it is at this third level of review that a healthcare provider can examine HHS's evidence obtained from discovery and cross-examine its witnesses.

To prevail on a procedural due process claim, a plaintiff must "show (1) a cognizable liberty or property interest; (2) the deprivation of that interest by some form of state action; and (3) that the procedures employed were constitutionally inadequate." *Iota* Xi Chapter of Sigma Chi Fraternity v. Patterson, 566 F.3d 138, 145 (4th Cir. 2009) (cleaned up). Only the third showing, however, is at issue in addressing Advantage Health's challenge to the constitutional adequacy of the administrative process in light of the long delay in providing the third level of that process — the ALJ hearing. To assess the constitutional adequacy of an opportunity to be heard, courts consider (1) the private interest affected by the official action; (2) the risk of an erroneous deprivation of that interest given the procedures used, as well as the probable value, if any, of additional or substitute procedural safeguards; and (3) the government's interest. See Mathews, 424 U.S. at 335. Thus, to succeed on the merits of its claim, Advantage Health must demonstrate that the absence of a prompt post-deprivation ALJ hearing creates an unacceptable risk of an erroneous deprivation.

Were there no alternative for review, a prompt post-deprivation hearing by an ALJ might arguably be required to mitigate the risk of an erroneous deprivation of Medicare reimbursements. But there is an alternative here. Specifically, the statutory process

provides for an ALJ hearing within 90 days, which, if delayed, may be bypassed to obtain a timely judicial hearing. No one has argued that *judicial review* under this escalation mechanism is untimely. As we stated in *Cumberland*:

Properly understood . . . the Medicare Act establishes a multilevel, coherent regulatory scheme, which authorizes a healthcare provider to bypass levels of review that are not completed in accordance with specified time frames and, at the same time, to create a record that it can ultimately use for judicial review. While the Act gives the Hospital System the clear and indisputable right to this administrative process, it does not give it a clear and indisputable right to adjudication of its appeals before an ALJ within 90 days.

816 F.3d at 56 (cleaned up). Thus, because the administrative process anticipates and accommodates potential delays in obtaining ALJ review, the due process validity of the process does not depend on the timeliness of an ALJ hearing.

Advantage Health argues nonetheless that *judicial review*, even if prompt, is not an adequate substitute for a timely ALJ hearing because an ALJ hearing offers additional procedural safeguards. Its argument, in essence, is that an ALJ hearing is the *sine qua non* of due process. But this argument relies on a faulty understanding of the relative benefits of an ALJ hearing and judicial review. First, it should be understood that the vast majority of ALJ hearings are conducted telephonically. *See* 82 Fed. Reg. 4974, 5045 (Jan. 17, 2017); *see also* 42 C.F.R. § 405.1020. Moreover, unless HHS or its contractors elect to become party to the proceedings, no discovery beyond what is contained in the administrative record — compiled at the first two review stages — can be compelled. *See* 42 C.F.R. § 405.1036(f)(1); *id.* §§ 405.1012, 405.1037(a). Similarly, cross examination is unavailable unless HHS chooses to participate in the proceedings and only as to individuals who choose to testify. *See id.* § 405.1036(f)(1). Indeed, as we noted in *Cumberland*,

healthcare providers are very limited in their ability to introduce new evidence at the ALJ hearing level. *See Cumberland*, 816 F.3d at 56 (citing 42 U.S.C. § 1395ff(b)(3), which requires "good cause" before a healthcare provider may present evidence to the ALJ that was not presented to the QIC). In short, there are no guarantees that Advantage Health would, at the ALJ hearing level, be able to introduce new evidence, to review any additional discovery, or to cross examine government witnesses, and thus the very procedural safeguards that Advantage Health argues are critical are far from assured even at the ALJ hearing level.

More fundamentally, Advantage Health's myopic focus on the delay in providing one specific procedural step fails to recognize, as we emphasized in *Cumberland*, that the administrative process must be considered as a comprehensive whole that ends with an opportunity for timely judicial review. Indeed, the integrated four-step process outlined in the Medicare Act specifically addresses the very delay to which Advantage Health objects through its escalation provisions. And Advantage Health does not ask us to strike down the statutory scheme as unconstitutional. *See Cumberland*, 816 F.3d at 56 (denying an attack on similar delays in the Medicare process because, among other reasons, it would "undermin[e] important separation-of-powers principles").

At bottom, while Advantage Health has elected not to avail itself of the escalation procedure in favor of pursuing delayed ALJ review, it cannot complain that its election denies it due process. Because the escalation procedure is specifically made part of the process to ensure a timely post-deprivation review *in a court of law*, Advantage Health cannot succeed on its procedural due process claim. And given that Advantage Health

failed to demonstrate a likelihood of success on the merits of its claim, the district court erred in granting its motion for a preliminary injunction.

IV

HHS also argues on appeal that the district court's findings with respect to the other requirements for a preliminary injunction — irreparable harm, balance of the equities, and public interest — were also erroneous. But because we conclude that Advantage Health has not demonstrated a likelihood of success on the merits, we need not reach these other arguments.

* * *

Accordingly, we vacate the district's preliminary injunction.

IT IS SO ORDERED.